

Comments on the Draft NARM Rulemaking & Secure Transfer

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Acronyms Used in Presentation

NARM \equiv Naturally occurring or Accelerator produced
Radioactive Material

CORAR \equiv Council on Radionuclides and
Radiopharmaceuticals

AU \equiv Authorized User

ANP \equiv Authorized Nuclear Pharmacist

PET \equiv Positron Emission Tomography

DAC \equiv Derived Air Concentration (Part 20)

ALI \equiv Annual Level of Intake (Part 20)

General Comments on NARM Rulemaking

- Staff has completed a tremendous amount of work in a short time frame.
- Staff has been very helpful and understanding to the medical community's needs.
- CORAR members are generally pleased with draft rulemaking.
- Rulemaking needs some minor fixes to assure smooth transition for medical community.

Favorable Sections of Draft Rulemaking

- Delineation of three types of cyclotrons and their handling in rulemaking is appropriate.
- Grandfathering of Part 35 AUs & ANPs will be helpful to licensees.
- NRC's waiver will allow seamless operations until final rule is in place.
- CORAR is pleased another workshop will be held for regulated community.

Concerns With Draft Rulemaking

- Although *Compatibility Level B* will provide some uniformity, CORAR fears some inconsistency among states will remain.
- Reciprocity between states needs to be improved.
- PET community needs specific DACs and ALIs for O-15 and N-13.

Concerns With Draft Rulemaking (Cont'd)

- Low energy (≤ 11 MeV) PET cyclotrons which are self-shielded should not be required to have financial assurance for decommissioning.
- PET community needs cyclotron operators and engineers recognized as Part 30 AUs as is done in several states, and be grandfathered.

Concerns With Draft Rulemaking (Cont'd)

- The new fee structure in Part 170 will negatively impact facilities located in non-Agreement states, which will now be under NRC's jurisdiction.

Comments on Secure Transfer Portion of EPAct

- CORAR feels radiopharmaceutical and medical radionuclide shipments do not warrant inclusion in *secure transfer* rulemaking.
- Congressional intent (from '03 cmte report) was to exclude these materials: “The NRC should focus particular attention on identifying radiopharmaceuticals and other medical materials for appropriate exemption from the new regulations, to assure the uninterrupted availability of these materials to patients that need them”

Comments on Secure Transfer Portion of EPA Act (Cont'd)

- Although CORAR has not seen the draft rulemaking, we understand it is NRC staff's intent to exclude these materials from the rulemaking.

Summary

- Thank you for opportunity to present our comments directly to you.
- We will continue to work with NRC staff on the NARM rulemaking.
- We hope we have the opportunity to directly interact with the Commission in the future.